

PATENT

Attorney Docket No.: 015280-415100US

Client Ref. No.: E-128-2000/0-US-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Samir N. Khleif *et al.*

Application No.: 09/810,310

Filed: March 14, 2001

For: METHODS AND COMPOSITIONS
FOR CO-STIMULATION OF
IMMUNOLOGICAL RESPONSES TO
PEPTIDE ANTIGENS

Customer No.: 45115

Confirmation No. 9099

Examiner: Marianne Dibrino

Technology Center/Art Unit: 1644

DECLARATION
UNDERBWP
015280-415100USCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Jay Berzofsky, declare and state as follows:

1. I am a co-inventor of the subject matter of U.S. Patent Application No. 09/810,310, entitled "Methods and Compositions for Co-stimulation of Immunological Responses to Peptide Antigens" (hereinafter "the '310 application" or "the application").

2. I currently hold the position of Chief, Vaccine Branch of the Center for Cancer Research at the National Cancer Institute, National Institutes of Health. I have a Ph.D. in Molecular Biology as well as an M.D. from the Albert Einstein College of Medicine. I have 34 years of post-graduate scientific and biomedical experience, including, for example, in the areas of antigen recognition by T lymphocytes; antigen processing and presentation; vaccine design and development based on immunological principles, peptide synthesis, and recombinant DNA technology; and AIDS, malaria, and cancer vaccines. I have also held editorial positions on several peer review scientific journals, including the Journal of Immunology, Journal of Molecular and Cellular Immunology, Molecular Immunology, Peptide Research, International

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Immunology, and Clinical Immunology, among others. I have co-authored over 410 scientific papers in the areas of molecular and cellular biology, immunology, and vaccine research. A copy of my curriculum vitae is attached hereto as Exhibit 1.

3. As a co-inventor of the subject matter described in the '310 application, and as a researcher in the fields of immunology and vaccine design (*see* ¶2), I am a person of skill in the art to which the invention as claimed in the application pertains.

4. I have read the Office Action dated May 17, 2007 ("Office Action") issued by Examiner Dibrino.

5. I understand from the Office Action that the pending claims 1, 2, 6, 11, 12 and 14-17 stand rejected as allegedly obvious over *Corr et al. (J. Exp. Med.* 184:1555-1560, 1996) (referred to hereafter as "Corr (1996)") in view of *Corr et al. (J. Immunol.* 159:4999-5004, 1997) (referred to hereafter as "Corr (1997)"). In addition, I understand from the Office Action that pending claims 7 and 8 stand rejected as allegedly obvious over *Corr (1996)* in view of *Corr (1997)* as applied to claims 1, 2, 6, 11, 12 and 14-17 above, and further in view of WO 99/45954 A1.

6. I have read and understand the documents referenced in ¶5 above.

7. I am a co-inventor of the WO 99/45954 reference, also discussed in the Office Action.

8. The statements set forth herein are offered to address the Examiner's remarks in the Office Action and to show that, as of the filing date of the '310 application, the scientific literature and the published patent application discussed in the Office Action would not have led an artisan of ordinary skill to the invention as presently claimed in the application.

9. I have reviewed *Corr (1996)* and understand the reference to describe the injection of a naked plasmid DNA directly into the muscle cells of mice. The mice were parent→F1 bone marrow chimeras in which H-2^{bnd} recipient mice received bone marrow that

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expressed only H-2^b or H-2^d MHC molecules. The plasmid injected into the mice encoded the nucleoprotein from the A/PR/8/34 influenza viral strain. This single viral antigen has epitopes for both the H-2D^b and H-2K^d molecules. The resulting CTL responses were restricted to the MHC haplotype of the bone marrow alone and not to the second haplotype expressed by the recipient mouse's monocytes. The authors of Corr (1996) described their data as showing that the mechanism of priming in their method for vaccination used the MHC from bone marrow-derived antigen presenting cells. None of the experiments described involved the injection of a soluble polypeptide or peptide antigen. The experiments also did not describe the injection of a naked DNA plasmid encoding a co-stimulatory molecule, such as a B7 molecule.

10. The Examiner states in the pending Office Action that Corr (1996) teaches intramuscular injection of a viral protein antigen mixed with naked plasmid DNA encoding B7.1 or B7.2 co-stimulatory molecule. In addition the Examiner states that Corr (1996) teaches that muscle cells at the site of injection do not present antigen to the immune system, but rather professional bone marrow-derived antigen presenting cells present the antigen that results in a CTL response to the antigen.

11. In my review of Corr (1996) I did not find any reference to the injection of a viral protein antigen mixed with naked plasmid DNA encoding a co-stimulatory molecule of any type, much less a B7 family member. Corr (1996) merely describes the injection of a naked DNA plasmid encoding a viral protein having epitopes for two different haplotypes. The plasmids were injected into the muscle of the mice to distinguish whether the muscle cells surrounding the injection site or the circulating antigen presenting cells present the antigen expressed by the transfected muscle cells from the naked plasmid. There is no suggestion or disclosure of the use of a naked plasmid DNA encoding a co-stimulatory molecule in inducing any sort of immune response.

12. The skilled artisan reading Corr (1996) would understand this reference as teaching that intramuscular injection of plasmid DNA encoding the influenza nucleoprotein results in the induction of an influenza nucleoprotein-specific cytotoxic T lymphocyte restricted to the MHC class I molecules expressed by circulating bone marrow-derived antigen presenting

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cells. No conclusion can be drawn as to what type of immune response might be induced by a polypeptide antigen injected into a muscle. Further, there is no information regarding the type of immune response that might be induced by either to injection of a combined composition with a naked plasmid expressing a co-stimulatory molecule and a naked plasmid expressing a polypeptide antigen or a combined composition with a naked plasmid expressing a co-stimulatory molecule and a soluble polypeptide antigen. Similarly, there is no information that discloses or suggests the type of immune response that might result from separate injections of the above compositions.

13. The Examiner alleges in the pending Office Action that Corr (1997) teaches the following:

- a) that co-expression of B7-1 in the vicinity of a minimal MHC class I-restricted antigen is sufficient to prime a cytotoxic T cell response;
- b) that expression of the MHC class I restricted epitope in the same cell as the costimulatory ligand is not imperative for T cell priming, but *in vivo* a T cell cannot be effectively primed with a cognate signal from a peripheral somatic tissue if a second signal stimulus is not available in the immediate vicinity, for example, in the same muscle;
- c) that *in vivo* transfection of peripheral somatic tissues with plasmids encoding costimulatory ligands not only enhanced immune responses to coinjected protein antigens, but also dramatically increased the immune response to coinjected protein antigens;
- d) that by increasing the density of membrane-bound costimulatory molecules, naked plasmid DNA injection can boost immune responses to soluble protein antigen in a manner analogous to conventional adjuvants, but without apparent systemic side effects;
- e) that the plasmid DNA were constructed with a promoter regulatory element for high expression.

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14. The Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have administered the viral protein antigen as taught by Corr (1996) or the CTL peptide epitope taught by Corr (1997) separately from the naked plasmid DNA encoding B7.1 and/or B7.2 to closely adjacent sites as taught by Corr (1997). Further, the Examiner alleges that the skilled artisan would be motivated to administer a naked plasmid DNA expressing a B7 co-stimulatory molecule coordinately with an immunologically effective amount of a peptide or protein antigen comprising one or more T cell epitope(s) separately to closely adjacent sites is equivalent to co-administration. The Examiner further alleges that the skill artisan would be motivated to use the method as claimed in the present invention for convenience and standardization between administrations because the same naked plasmid DNA preparation administered separately could be used for co-ordinate immunizations with different protein or peptide antigens. Still further, the Examiner alleges that Corr (1997) teaches that co-expression of B7-1 in the vicinity of a minimal MHC class I-restricted antigen is sufficient to prime a CTL response, including where the antigen is a protein antigen.

15. In my review of Corr (1997) I found that teaches the co-administration of naked plasmid DNA encoding a B7-1 or B7-2 co-stimulatory molecule with a naked plasmid DNA encoding a MHC class I-restricted peptide primed a specific CTL response. This teaching is set forth in statement (a) by the Examiner in paragraph 14 above. Co-administration of the naked plasmid DNA encoding a B7-1 or B7-2 co-stimulatory molecule with ovalbumin protein at the same site intramuscularly induced an antibody response, not an antigen specific CTL response as alleged by the Examiner. It is in the context of this increase in antibody response that the authors of Corr (1997) conclude that by increasing the local density of membrane bound costimulatory molecules, naked DNA injection can boost immune responses to soluble antigen in a manner analogous to conventional adjuvants. (See page 5001 last paragraph bridging to page 5002). There is no disclosure or suggestion in Corr (1997) that co-administration of naked plasmid DNA encoding a B7 co-stimulatory molecule with a soluble protein antigen or a soluble peptide antigen even at the same site could induce an antigen specific CTL response much less when administered at a separate site. Further, at page 5002, right column, lines 27-30 of the

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Discussion the authors conclude that "[b]oth minigene and a co-stimulator gene must be injected into the same muscle site for CTL induction, whereas injection into separate muscles does not induce a response." Again, there is no disclosure or suggestion relating to the induction of a CTL response with co-administration of a co-stimulator gene and a protein or peptide having a CTL epitope. These results are consistent with the understanding in the art that soluble proteins typically induce a type II response and not a type I CTL response.

16. The reasons of the Examiner as set forth in ¶ 14 do not provide sufficient basis for motivating the skilled artisan to the invention recited in the pending claims. In particular, Corr (1996) does not suggest or disclose the administration of a protein or peptide at all. In fact, as stated above, Corr (1996) disclose the administration only of a naked plasmid DNA. Further, Corr (1997) does show that co-expression of DNA encoding B7-1 and DNA encoding a polypeptide having a T cell epitope can result in the processing of a MHC class I-restricted antigen to prime a CTL response. As above, co-administration of a plasmid encoding either B7-1 or B7-2 with ovalbumin at the same site resulted in the induction of an antigen specific antibody response, not a cytotoxic T cell response. Administration of a mixture of a plasmid encoding a co-stimulatory molecule, such as a B7 family member, and either a plasmid encoding a polypeptide having a T cell epitope or a soluble protein having a B cell epitope is not the same as the separate administration of a soluble peptide having a T cell epitope and a DNA plasmid encoding B7 at closely adjacent sites.

17. The Examiner has also combined Corr (1996) and Corr (1997) with the disclosure of WO 99/45954 A1 to reject claims 7 and 8 as obvious. In this rejection, the Examiner alleges that the teachings of the combined Corr references described above do not teach viral antigen from HBV, HSV, or HPV. But, that the alleged teachings of WO 99/45954 include epitopes on antigens from, for example, HBV, HCV, HPV and HSV that are useful in pharmaceutical compositions for both therapeutic and diagnostic methods, and that further teachings disclose that the identified peptides bind to class I HLA molecules. It is alleged by the Examiner that an artisan of ordinary skill would be motivated to utilize the epitopes and proteins

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disclosed in WO 99/45954 in the "improved" methods for generating an effective immune response.

18. As above, I have reviewed the Corr (1996) and Corr (1997). Corr (1996) does not teach a method for co-administration of a naked DNA encoding a B7 co-stimulator molecule with a peptide antigen of any kind. Further, the only teachings in Corr (1997) that relate to the co-administration of a naked DNA encoding a B7 co-stimulatory molecule and a polypeptide or protein disclose the induction of an antibody response and not an antigen specific cytotoxic T cell response. As such, there is no disclosure or suggestion to one of ordinary skill in the art to combine the references with any epitope or antigen disclosed in WO 99/4594 A1 to separately inject a naked DNA encoding a B7 co-stimulatory molecule to a closely adjacent site to induce an antigen specific CTL response.

19. It is my opinion that at the time of filing of the instant application, for *in vivo* administration of two separate agents targeting the same cell, it was typical to use the agents together as an admixture, rather than as individual formulations administered separately. In the absence of any specific teaching or suggestion to the contrary, and assuming (for argument's sake) a general teaching of *in vivo* administration, one of skill in the art would be led to administer B7 DNA and peptide antigen molecules together as an admixture, or coupled, but not separately. The teaching in Corr (1997) was that the two components had to be mixed in the same syringe for injection, not at closely adjacent sites, and that they did not work at more distant sites. Fig. 4 of Corr (1997) demonstrated a successful result only when the plasmids were mixed, not given at separate sites. Also, the experiment described in Fig. 5 of Corr (1997) showed the induction of antibody only when the protein and plasmid encoding B7 were mixed and injected together in the same site, not at separate sites. In addition, the experiment as described in Fig. 5 did not address a CTL response at all. Therefore, one of skill in the art would learn from Corr (1997) that separate sites are not effective and that only admixture works for both antibody and CTL responses. This study did not address at all separate administration of a soluble peptide or the administration of even two plasmids at closely adjacent but separate sites.

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20. None of the proposed motivations enumerated by the Examiner are specific enough or have sufficient force to lead one of ordinary skill in the art to the particular invention as presently claimed in the application. These proposed motivations do not specifically lead the artisan to administration of a peptide antigen and nucleic acid encoding B7 separately at closely adjacent sites.

21. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that I make these statements with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize validity of the application or any patent issuing therefrom.

Executed this 16th day of October, 2007

By:



Name: Jay A. Berzofsky, M.D., Ph.D.

Title: Chief, Vaccine Branch of the Center
for Cancer Research, National
Cancer Institute, National Institutes
of Health

CURRICULUM VITAE

Name: Jay Arthur Berzofsky

Date and Place of Birth: April 13, 1946, Baltimore, Maryland

Marital Status: Married to Sharon M. Miller; two children
Alexander, April 30, 1974, and Marcus, May 27, 1976

Education:

1967 - A.B., Harvard University (Summa Cum Laude in Chemistry)
1971 - Ph.D., Albert Einstein College of Medicine, Molecular Biology
1973 - M.D., Albert Einstein College of Medicine, Medical Scientist
Training Program

Brief Chronology of Employment:

1973 - 1974	Medical Internship (Straight Medicine), Massachusetts General Hospital, Boston, Massachusetts
1974 - 1976	Research Associateship, Laboratory of Chemical Biology National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health
1976 - 1979	Investigator ("Expert"), Metabolism Branch, National Cancer Institute, National Institutes of Health
1979 - 1987	Senior Investigator, Metabolism Branch, National Cancer Institute, National Institutes of Health
1987 - 2003	Chief, Molecular Immunogenetics and Vaccine Research Section, Metabolism Branch, National Cancer Institute, National Institutes of Health
2004 - Date	Chief, Vaccine Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health

Honors/Awards:

Detur Prize, Harvard University, 1964
Harvard College Scholarship, Harvard University, 1964
Phi Beta Kappa, Junior Year, Harvard University, 1966
Summa Cum Laude in Chemistry, Harvard University, 1967
Sophia Freund Prize for Graduate with Highest Cumulative Grade Point
Average, Harvard College, 1967
NIH Special Achievement Award, 1982
Hollister - Stier's Distinguished Lectureship, Washington State

University, 1986
 J. W. McLaughlin Fund Distinguished Contributions to Immunology Lectureship,
 University of Texas Medical School, Galveston, 1987
 U. S. Public Health Service Superior Service Award, 1988
 31st Michael Heidelberger Award and Lecture, Columbia University, 1992
 McLaughlin Visiting Professorship, University of Texas Medical School,
 Galveston, 1992
 American Society for Clinical Investigation, President 1993-94
 Fellow of the American Association for the Advancement of Science, 1995
 Cytokine Interest Group Best Paper of 2000 Award to fellow in lab, 2001
 The 2004 Tadeusz J. Wiktor Memorial Lecture, Wistar Institute, University of
 Pennsylvania, Philadelphia, PA., November 17, 2004
 Chair, Medical Sciences Section, American Association for the Advancement of Science,
 2007-2008
 The Herschel Zackheim Lectureship Award, International Society for Cutaneous
 Lymphomas, 2007
 Distinguished Alumnus of the Year Award 2007, Albert Einstein College of Medicine

Professional Society Memberships:

Association of Harvard Chemists, 1967 - present
 New York Academy of Sciences, 1971 - present
 American Association of Immunologists, 1977 - present
 Undersea Medical Society, 1978 - 1988
 American Federation for Clinical Research, 1979 - present
 American Society of Biological Chemists, 1980 - present
 American Society for Clinical Investigation, 1983 - present,
 Secretary-Treasurer, 1989 - 1992
 President-elect, 1992-1993
 President, 1993-94
 Association of American Physicians, 1990 – present
 American Association for the Advancement of Science, Fellow; Chair of Medical
 Sciences Section, 2007-2008
 Faculty of 1000, 2006-present

Editorial Positions:

Associate Editor, *Journal of Immunology*, 1980 - 1984
 Editorial Advisory Board, *Journal of Molecular and Cellular Immunology*, 1983-88
 Advisory Editor, *Molecular Immunology*, 1985 - 1988
 Editorial Board, *Peptide Research*, 1987 - present
 Transmitting Editor, *International Immunology*, 1988 - 2000
 Editorial Board, *Journal of Human Virology*, 1997-present
 Consulting Editor, *Journal of Clinical Investigation*, 1998-2005
 Section Editor, *Clinical Immunology*, 2002-present
 Associate Editor, *Clinical Cancer Research*, 2002-present

Professional Committees and Activities:

American Association of Immunologists, Membership Committee, 1981 - 1988
 American Association of Immunologists, Chairman of Membership Committee, 1983 - 1988
 NIH Clinical Center Compensable Events Committee, 1982 - present
 American Society for Clinical Investigation, Council, 1989-1994
 NCI Division of Clinical Sciences Promotion and Tenure Committee, 1995-2001.
 NCI Division of Clinical Sciences Research Advisory Group, 1995-2001
 NCI Director's Intramural Advisory Board, 1997-99
 NIH AIDS Vaccine Research Center Steering Committee, 1997-present
 NIH Search Committee for Director of Office of AIDS Research, 1997-98
 NIAID Malaria Vaccine Task Force, 1998-present
 NCI Vaccine Working Group, Chairman/Organizer, 1998-present
 NCI/CCR Immunology Faculty Steering Committee, 2001-present
 NCI/CCR HIV & Virology Faculty Steering Committee, 2001-present
 NCI/CCR Frontiers in Science Newsletter Editorial Board, 2001-present.
 NCI/NIH Committee for Biodefense, founding member, 2001-present.
 NCI Center of Excellence in Immunology, Steering Committee, 2003-present.
 NIH CRADA 01361 with Genzyme Corporation. Co-principal Investigator, 2003-present
 Advisory Committee, Harvard Blood Center, 2004-present
 External Advisory Committee, University of London, 2006-present.
 NIH Director's Biennial Report to Congress, 2007, Team Leader for Cancer topic.

Military Service:

Commissioned Corps, United States Public Health Service, 1974 - 1976

Other Research Experience:

Summers, 1962 - 1965 Research Assistant, Pediatric Research Unit (H. M. Nitowsky), Sinai Hospital, Baltimore, Maryland
 Summer, 1966 Research Assistant, Organic Synthesis Laboratory (C. H. Robinson), Department of Pharmacology, Johns Hopkins School of Medicine, Baltimore, Maryland
 Summer, 1967 Visiting Scientist, Laboratoire d'Enzymologie (G. N. Cohen), Centre National de la Recherche Scientifique, Gif-sur-Yvette, France

Medical Licensure: Maryland and Massachusetts

Major Outside Activities (Not permitted by NIH after 2005)

Medimmune, Inc.—Scientific Founder and Chair, Scientific Advisory Board, 1989-2002
 Magainin Pharmaceuticals, Inc.—Member, Scientific Advisory Board, 1991-97
 Diacrin, Inc.—Member, Scientific Advisory Board, 1993-2002
 Pharmadyne, Inc.—Scientific Co-Founder and Chair, Scientific Advisory Board, 1997-2004
 Boston University Community Technology Fund—Consultant, 1997-1999
 Health Care Ventures, Inc.—consultant, 1998

EMD Pharmaceuticals, Inc.—consultant, 2000-2003
 Epivax, Inc.—Member, Scientific Advisory Board, 2000-2004
 Therapeutic Devices, Inc.—consultant, 2002-2004
 Transform Pharmaceuticals, Inc.—consultant 2002-2005
 Celera Genomics, Inc.—consultant 2002-2004
 Genencor International, Inc.—consultant 2003-2004.

Major areas of research:

1. Molecular basis of antigen recognition by T lymphocytes
2. Processing of antigens and their presentation by major histocompatibility molecules
3. Structure of antigenic sites on protein antigens
4. Genetic regulation of the immune response
5. Design and development of artificial vaccines based on immunological principles and peptide synthesis or recombinant DNA technology
6. AIDS vaccines and diagnostic techniques
7. Malaria vaccines
8. Cancer vaccines
9. Antigen-antibody interactions
10. Structure-function relationships in proteins and protein conformation.
11. Regulation of tumor immunosurveillance and T cell function by cytokines
12. Mucosal immunity and vaccines

BIBLIOGRAPHY

Jay Arthur Berzofsky

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Patent Applications Filed, Patents Issued & Technology Transfer

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- Berzofsky, J. A., Ouyang, C. S., DeLisi, C., Margalit, H., Cornette, J. L., and Cease, K. B. Synthetic peptides which induce cellular immunity to the AIDS virus and AIDS viral proteins. Filed December 30, 1986. Application No. 06/947,935. CIP 07/492,318. Patent 5,081,226 issued January 14, 1992.
- Good, M. F., Berzofsky, J. A., and Miller, L. H. Improved malarial immunogen. Filed February 26, 1987. Application No. 07/019,000. Patent Number 4,886,782 issued December 12, 1989.
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- Good, M. F., Kumar, S., Berzofsky, J. A., and Miller, L. H. Synthetic vaccine against P. falciparum malaria. Filed July 7, 1988. Application No. 07/216,088. Patent 5,028,425 issued July 2, 1991.
- Berzofsky, J. A., Hale, P. M., Hosmalin, A., Margalit, H., Spouge, J. L., and Cornette, J. L. Synthetic vaccine against AIDS virus. Filed July 21, 1988. Application No. 07/222,684. Patent 5,030,449 issued July 9, 1991.
- Berzofsky, J. A., Kurata, A., Palker, T. J., and Haynes, B. F. Immunodominant sites of HTLV-I envelope protein. Filed September 1, 1989. Application No. 07/401,441. Patent 5,622,703 issued April 22, 1997. Patent 5,695,762 issued Dec. 9, 1997.
- Berzofsky, J. A., Hosmalin, A., Clerici, M., Germain, R. N., Shearer, G. M., Moss, B., and Pendleton, C. D. Peptides stimulating cytotoxic T cells immune to HIV RT. Filed March 9, 1990. Application No. 07/489,825. Patent 5,336,758 issued August 9, 1994.

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Shearer, G.M., Berzofsky, J.A., and Clerici, M. Test of HIV-specific T lymphocyte function that detects exposure to HIV antigens and possibly early HIV infection. Filed May 14, 1992. Application No. 07/882,078.

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Berzofsky, J.A., Yanuck, M., Takahashi, H., Carbone, D.P., and Minna, J.D. Novel Immunotherapeutic Methods and Vaccines. Filed March 15, 1993. Application No. 08/031,494.

Berzofsky, J.A., Ahlers, J.D., Pendleton, C.D., Nara, P., and Shirai, M. Composite synthetic peptide construct eliciting neutralizing antibodies and cytotoxic T lymphocytes against HIV. Filed May 14, 1993. Application No. 08/060,988. U. S. Patent 5,932,218 issued August 3, 1999. European Patent 0701572 B1, issued August 11, 1999. Divisional: Multideterminant peptides that elicit helper T lymphocyte, cytotoxic T lymphocyte, and neutralizing antibody responses against HIV-1. U.S. Patent 6,294,322 B1 issued Sept. 25, 2001.

Berzofsky, J.A., Feinstone, S., and Shirai, M. Hepatitis C virus core peptide for stimulation of cytotoxic T lymphocytes and diagnosis of HCV exposure. Filed April 8, 1994. Application No. 08/224,973. European patent 0754193 issued June 14, 2000.

Goletz, T.J., Berzofsky, J.A., and Helman, L.J. Novel immunotherapeutic methods and vaccines. Filed September 15, 1995. Application No. 08/528,129. Notice of allowance April 14, 1999. U.S. Patent 5,997,869 issued December 7, 1999.

- Klimpel, K., Goletz, T.J., Arora, N., Leppla, S.H., and Berzofsky, J.A. Targeting antigens to the MHC class I processing pathway with an Anthrax toxin fusion protein. Filed September 17, 1996. Application No. 60/025,270. US Patent 6,592,872 issued July 15, 2003.
- Berzofsky, J.A., Belyakov, I.M., Derby, M.A., Kelsall, B.L., and Strober, W. Mucosal cytotoxic T lymphocyte responses. Filed September 11, 1997. Application 60/058,523. Divisional 10/815,340 filed April 15, 2004. Patent 6,749,856 issued June 15, 2004. European Patent 1011720 issued Dec. 29, 2004.
- Berzofsky, J.A., Sarobe, P., Major, M., Feinstone, S.H. Modified HCV peptide vaccine. Filed Aug. 21, 1998. Application 60/097,446. Application 09/763,260 filed Oct. 19, 2001 as continuation. US Patent 6,685,944 issued February 3, 2004.
- Berzofsky, J. A., M. Terabe, D. D. Donaldson, S. Matsui, N. Noben-Trauth, and W. E. Paul. Method and composition for enhancing an immune response. Filed October 20, 2000. Application 90/693,600.
- Terabe, M., S. Matsui, J.A. Berzofsky. Methods to Prevent Tumor Recurrence by Blockage of TGF-Beta. Application US 60/421,286. Filed October 25, 2002. PCT International Application PCT/US03/34023 Filed October 24, 2003.
- Morris, J., J.A. Berzofsky, Y. Sakai, J.-M. Park, M. Terabe. Methods for Prophylaxis and Treatment of HER-2/neu Tumors. Provisional application filed 2002.
- Perera, L. P., T. A. Waldmann, S. Oh, J. A. Berzofsky. Recombinant Vaccinia Viruses Expressing IL-15 and Methods of Using the Same. Application #: U.S. Provisional 60/433,703. Filed December 16, 2002.
- Berzofsky, J. A., and T. Okazaki. Enhanced HIV-1 Vaccines and Methods for Their Use. U.S. Provisional Application 60/459,507, filed March 31, 2003.
- Berzofsky, J.A., I. Pastan, S. Oh. Immunogenic Peptides and Peptide Derivatives for Prostate and Breast Cancer Treatment. Application # 60/476,467. Filed June 5, 2003. National Stage US Patent Application 10/559,329 filed December 2, 2005.
- Berzofsky, J.A., J. T. Snyder, II, A. Dzutsev, and I. M. Belyakov. Peptides for the induction of an immune response to vaccinia virus and their use. Application 60/512,039. Filed October 16, 2003.
- Berzofsky, J.A., I. H. Pastan, and M. Terabe. Immunogenic peptides of XAGE-1. Application # 60/529,025. Filed December 12, 2003. International PCT/US2004/041639 filed December 13, 2004.

Berzofsky, J.A., and T. Okazaki. Epitope-Enhancement of a Human CD4 HIV Epitope. Application # 60/567,073, filed on April 30, 2004

Catanzaro, A., R. Yarchoan, J. A. Berzofsky, T. Okazaki, J. T. Snyder, and S. Broder. Vaccines and Methods for Prevention and Treatment of Drug-Resistant HIV-1 and Hepatitis B Virus. Application 60/655,984 pending, filed Feb. 22, 2005.

Terabe, M., S. Takaku, and J. A. Berzofsky. Synergistic effect of TGF-beta blockade and immunogenic agents on tumors. U.S. Patent Application No. 60/654,329, filed February 17, 2005.

NIH CRADA 01361 with Genzyme Corporation (2003-date). Co-principal Investigator

Jay A. Berzofsky
Speaking and Chairmanship Invitations
1990-2007

1990

- 27 Jan.-3 Feb., 1990 UCLA Symposium on Cellular Immunity and the Immunotherapy of Cancer, Park City, Utah. Invited plenary session speaker.
- 5 Feb., 1990 Walter Reed Army Institute of Research AIDS Conference, Washington, D.C., Invited speaker.
- 2 March, 1990 University of Pennsylvania School of Medicine, Philadelphia, PA, seminar speaker.
- 1-7 April, 1990 UCLA Symposium on HIV and related Retroviruses, Keystone, CO. Invited plenary session speaker.
- 3-7 June, 1990 American Association of Immunologists, FASEB, Meeting, New Orleans, LA. Invited symposium chairperson (Antigen Processing and Presentation) and symposium speaker.
- 20-24 June, 1990 Sixth International Conference on AIDS, San Francisco, CA. Invited plenary session speaker on Vaccines.
- 8-12 July, 1990 Symposium on Antigen Presenting Cells organized by the University of Vienna, Baden bei Wien, Austria. Invited speaker.
- 11-17 Aug., 1990 Laboratory of Tumor Cell Biology Meeting on AIDS and Human Retroviruses, Bethesda, Md. Invited speaker and session chairperson.
- 9-12 Sept., 1990 European Federation of Immunological Societies Meeting, Edinburgh, Scotland, U.K. Invited plenary session speaker.
- 19 Oct., 1990 University of Massachusetts Medical School, Worcester, MA. Invited seminar speaker.
- 29-30 Oct., 1990 NCI Cancer Vaccine Workshop, Bethesda, MD. Invited speaker.
- 15-16 Nov., 1990 New Horizons in Immunology Symposium, organized by *Nature*, Boston, MA. Invited speaker.
- 4 Dec., 1990 National Academy of Sciences Institute of Medicine Meeting on Malaria, Washington, D. C. Invited speaker.

1991

- 12-17 March, 1991 Keystone Symposium on Immunotoxins, Denver, CO. Invited Plenary Speaker.
- 17 April, 1991 Harvard Medical School, Immunology Program, Boston, MA. Invited speaker.
- 3-6 May, 1991 Association of American Physicians, Seattle, WA. HIV session speaker.
- 17-18 May, 1991 Columbia University/Progenics Conference on AIDS, Arden House, NY. Invited speaker.
- 16-21 June, 1991 7th International Conference on AIDS, Florence, Italy. Invited speaker.
- 1-8 Sept., 1991 Laboratory of Tumor Cell Biology Retrovirus Meeting, Bethesda, MD. Invited speaker and session chairperson.
- 19-23 Sept., 1991 Cold Spring Harbor Vaccine Conference, Cold Spring Harbor, NY. Invited opening speaker.
- 15-19 Oct., 1991 Queensland Institute for Medical Research, Bancroft Center Opening Symposium, Brisbane, Queensland, Australia. Invited Plenary Keynote Speaker.
- 15 Nov., 1991 NIH Technology Transfer Symposium, Bethesda, MD. Invited speaker.
- 22 Nov., 1991 University of Virginia School of Medicine, Dept. of Microbiology, Charlottesville, VA. Invited speaker.

1992

- 10 January, 1992 Uniformed Services University of the Health Sciences, Bethesda, MD. Immunology course guest lecturer on Ir genes, and antigen processing and presentation.
- 4 February, 1992 National Cancer Institute, Experimental Immunology Branch, Bethesda, MD. Invited guest seminar speaker.
- 12 February, 1992 National Institute of Diabetes, Digestive, and Kidney Diseases, Laboratory of Chemical Biology, Bethesda, MD. Invited seminar speaker.
- 27 Mar.-4 Apr., 1992 Keystone Symposium on Prevention and Treatment of AIDS, Keystone, CO. Invited plenary speaker.
- 27 May, 1992 Columbia University College of Physicians and Surgeons, New York, NY. 31st Michael Heidelberger Award and Lecture.

- 5 June, 1992 Tufts University School of Medicine, Department of Medicine, Boston, MA. Invited Grand Rounds speaker.
- 13 July, 1992 National Cancer Institute, Laboratory of Tumor Cell Biology, Bethesda, MD. Invited seminar speaker.
- 9-16 Aug., 1992 National Cancer Institute, LTCB Annual Symposium on Human Retroviruses, Bethesda, MD. Invited speaker and session chairperson.
- 23-28 Aug., 1992 8th International Congress of Immunology, Budapest, Hungary. Invited chairperson of Workshop on Antigen Processing and Presentation, and speaker.
- 29-31 Aug., 1992 Symposium on Prediction and Recognition of Antigenic Determinants, Eötvös University, Budapest, Hungary. Invited plenary speaker and chairperson.
- 21-22 Sept., 1992 NIH Research Festival, Bethesda, MD. Invited session chairperson and speaker.
- 19-20 Oct., 1992 University of Texas Medical Branch, Galveston, TX. McLaughlin Visiting Professor.
- 20-23 Oct., 1992 54th Annual MD Anderson Symposium on the Immunobiology of Cancer, Houston, TX. Invited plenary speaker.
- 1993**
- 21-24 Jan., 1993 New York Academy of Sciences Symposium on the Specific Immune Treatment of Cancer, Washington, DC. Invited plenary speaker.
- 8-14 Feb., 1993 Keystone Symposium on Antigen Processing and Presentation, Taos, NM, Invited plenary speaker.
- 17-24 March, 1993 Joint Keystone Symposia on Cellular Immunity and Immunotherapy of Cancer, and on the Molecular Immunology of Virus Infections, Taos, NM. Invited joint plenary session speaker.
- 19-29 April, 1993 CBER-FDA Workshop on HIV Vaccines, Bethesda, MD. Invited speaker.
- 28-30 July, 1993 FDA Workshop on Combination Vaccines, Bethesda, MD. Invited speaker.
- 22-28 Aug., 1993 Laboratory of Tumor Cell Biology Annual Retrovirus Meeting, Bethesda, MD. Invited speaker and chairperson.

20-24 Sept., 1993 Cold Spring Harbor Symposium on Vaccines including the Prevention and Treatment of AIDS, Cold Spring Harbor, NY. Invited opening plenary speaker.

1-4 Nov., 1993 National Cooperative Vaccine Development Meeting on Advances in AIDS Vaccine Development, Division of AIDS, NIAID, Alexandria, VA. Invited speaker.

5-7 Nov., 1993 Project Inform/Immune Restoration Think Tank on HIV Treatment, Baltimore, MD. Invited Discussant.

10 Dec., 1993 Institute of Medicine Symposium "Towards an Understanding of the Correlates of Protective Immunity to HIV Infection," Washington, DC. Invited participant.

1994

23-30 Jan., 1994 Keystone Symposium on HIV, Hilton Head Island, SC. Invited plenary speaker.

13-30 Feb., 1994 Keystone Symposium on Human Tumor Viruses, Taos, NM. Invited plenary speaker.

29 Apr.-2 May, 1994 American Society for Clinical Investigation, Baltimore, MD. Presidential address.

18-19 July, 1994 Conference on Novel HIV Vaccine Strategies, Washington, D.C. Invited plenary speaker.

19-21 Sept., 1994 NIH Research Festival, Bethesda, MD. Invited speaker.

25-30 Sept., 1994 Laboratory of Tumor Cell Biology Annual Retrovirus Meeting, Bethesda, MD. Invited speaker and chairperson.

5-9 Oct., 1994 Cold Spring Harbor Meeting on Molecular Approaches to the Control of Infectious Diseases, Cold Spring Harbor, NY. Invited keynote speaker.

1995

16-23 Jan., 1995 Keystone Symposium on Molecular Aspects of Viral Immunity, Keystone, CO. Invited plenary speaker.

25-27 Jan., 1995 Jennifer Jones Simon Foundation Workshop on Cancer Immunotherapy, Los Angeles, CA. Invited discussant.

- 29 Jan-2 Feb, 1995 American Society for Microbiology Second National Conference on Human Retroviruses and Related Infections, Washington, DC. Invited speaker.
- 9 Feb., 1995 National Cancer Institute, Pediatric Oncology Branch, NIH, Bethesda, MD. Invited seminar speaker.
- 3-5 Mar., 1995 Second International Conference on Engineered Vaccines for AIDS and Cancer, San Francisco, CA. Invited plenary speaker.
- 19 May, 1995 University of Michigan, Dept. of Medicine, Ann Arbor, MI. Ground Rounds speaker.
- 23-29 July, 1995 9th International Congress of Immunology, San Francisco, CA. Invited plenary symposium chairperson and speaker.
- 27 Aug-2 Sept, 1995 Laboratory of Tumor Cell Biology Annual Retrovirus Meeting, Bethesda, MD. Invited chairperson and speaker.
- 6-9 Sept., 1995 Queensland Institute for Medical Research Golden Jubilee Symposium, Brisbane, Australia. Invited plenary speaker.
- 10-23 Sept., 1995 Australasian Society for Immunology Visiting Speaker, Melbourne, Canberra, and Sydney, Australia, and Dunedin and Auckland, New Zealand.
- 10 Nov., 1995 Emory University, Dept. of Microbiology and Immunology, Atlanta, GA. Invited seminar speaker.
- 30 Nov-3 Dec, 1995 First International Antigen Processing and Presentation Conference: Fundamental Mechanisms and their Application, Los Angeles, CA. Invited speaker.
- 16-19 Dec., 1995 Winter Advanced Course in Immunology and Infectious Disease, Tsuruoka, Japan. Invited faculty member/speaker.

1996

- 26-27 Feb., 1996 IBC Vaccine Technology Conference, Washington, DC. Invited speaker
- 25 Mar., 1996 CHI Symposium on New Cancer Strategies: p53 Diagnostics and Therapy, Washington, DC. Invited speaker.
- 26 Mar., 1996 Institute of Medicine Vaccine Workshop, Washington, DC. Invited speaker.
- 17-20 Apr., 1996 British Society for Immunology Jenner Bicentenary Symposium, Bristol, UK. Invited plenary speaker.

- 7-13 Sept., 1996 Institute of Human Virology Annual Retrovirus Meeting, Baltimore, MD.
Invited speaker.
- 1-3 Oct., 1996 NIH Intramural Immunology Retreat, Airlie, VA. Invited workshop chair.
- 25-27 Oct., 1996 University of Rome Cancer Immunotherapy Symposium, Rome, Italy.
Invited speaker.
- 23-27 Nov., 1996 Japan Immunology Society Jenner Bicentenary Symposium, Yokohama,
Japan. Invited plenary speaker.

1997

- 22 Jan., 1997 AIDS Malignancies Working Group Symposium, Washington, DC.
Invited speaker.
- 1-7 Feb., 1997 Keystone Symposium on Cellular Immunology and Immunotherapy of Cancer,
Copper Mountain, CO. Invited plenary speaker.
- 3-4 Mar., 1997 University of Alabama at Birmingham, Dept. of Medicine Trainee
Research Symposium, Invited Keynote Speaker.
- 23-25 Mar., 1997 Symposium on Immunogenicity of Proteins, Genentech, South San
Francisco, CA. Invited speaker.
- 9 Apr., 1997 NCI Grand Rounds Speaker, Bethesda, MD (Construction of Engineered
Vaccines for HIV).
- 13-19 Apr., 1997 Keystone Symposium on Tolerance and Autoimmunity, Keystone, CO.
Invited workshop chair.
- 30 Apr.-2 May, 1997 2nd National Symposium on Basic Aspects of Vaccines, Bethesda, MD.
Invited session chairperson and plenary speaker.
- 15-21 Sept., 1997 Institute of Human Virology Annual Meeting, Baltimore, MD. Invited
State-of-Art Lecturer.

1998

- 14 Jan., 1998 NIDR Invited Lecture, Bethesda, MD.
- 5-8 March, 1998 UCLA Symposium "Towards an HIV Vaccine: Immunopathogenesis of
HIV Infection," Palm Springs, CA. Invited plenary speaker.

- 13-19 March, 1998 Keystone Symposium on HIV Pathogenesis and Treatment, Park City, Utah. Invited speaker.
- 27 March, 1998 Georgetown University Lombardi Cancer Center, Washington, D.C. Invited speaker.
- 3 June, 1998 Wistar Institute, University of Pennsylvania, Philadelphia, PA. Invited speaker.
- 16 June, 1998 Bio'98 Symposium, New York, NY. Invited symposium speaker.
- 23-29 Aug., 1998 Institute of Human Virology Annual Meeting, Baltimore, MD. Invited State-of-Art Lecturer
- 18-22 Oct., 1998 5th International Union of Biochemistry and Molecular Biology Conference on the Biochemistry of Health and Disease, Jerusalem, Israel. Invited Symposium Speaker.
- 25 Oct., 1998 Weizmann Institute of Science, Rehovot, Israel, Invited seminar speaker.
- 26 Oct., 1998 University of London Medical School, Guy's Hospital, Invited seminar speaker.
- 1-6 Nov., 1998 10th International Congress of Immunology, New Delhi, India. Invited Symposium Speaker.
- 18-20 Nov., 1998 NMHCC Conference on Functional Antigenics, Washington, D.C. Invited speaker.
- 10-11 Dec., 1998 FDA-NCI Workshop on Tumor Vaccines, Bethesda, MD. Invited speaker.

1999

- 7-13 Jan., 1999 Keystone Symposium on HIV Vaccine Development, Keystone, CO. Invited speaker
- 16 March, 1999 University of Pittsburgh School of Medicine, Invited seminar speaker
- 12-17 April, 1999 Keystone Symposium on DNA Vaccines, Snowbird, Utah. Co-organizer and invited plenary speaker.
- 21-23 April, 1999 5th National Symposium on the Basic Aspects of Vaccines, Bethesda, MD. Invited plenary session chair and speaker.
- 6 May, 1999 Workshop on Alloimmunization as a Strategy for Vaccine Design against HIV/AIDS, Bethesda, MD. Invited speaker.

7-9 June, 1999 6th International Symposium on Hepatitis C and Related Viruses, Bethesda, MD.
Invited plenary speaker.

30 Aug-3 Sept 1999 Institute of Human Virology Annual Meeting, Baltimore, MD. Invited
State-of-Art Lecturer

8-10 Sept., 1999 International Congress on Cytokines, Bethesda, MD. Invited speaker.

13 Dec., 1999 Hôpital Cochin INSERM Unit, Paris, France. Invited seminar speaker.

13-15 Dec., 1999 Club Francophone des Cellules Dendritiques Symposium, Paris, France.
Invited plenary speaker.

2000

21-27 Jan., 2000 Keystone Symposium on Cellular Immunology and Immunotherapy of
Cancer, Santa Fe, NM, Invited Workshop Chairperson and speaker.

8-12 March, 2000 2nd Sabin Vaccine Foundation Walker's Cay Colloquium on
Immunotherapy of Cancer, Invited Speaker

6 April, 2000 New York Blood Center, New York, NY. Invited seminar speaker.

3-5 May, 2000 6th National Symposium on the Basic Aspects of Vaccines, Bethesda,
MD. Invited plenary session chair and speaker.

11 May, 2000 NIH Cytokine Symposium, Bethesda, MD. Invited Speaker

12-16 July, 2000 Mid-Summer Symposium on Hepatitis C Virus Vaccines, Jamaica.
Invited speaker and session organizer/chair

10-15 Sept., 2000 Inst. of Human Virology Annual Mtg, Baltimore, MD. Invited State-of-
Art Lecturer

22 Sept., 2000 NCI Symposium on Bench to Bedside and Back, Basic and Translational
Biomedical Research, Bethesda, MD. Organizer and Chair.

2 Nov., 2000 NIH Collaborative Meeting on HIV Vaccines, Bethesda, MD. Invited
Speaker.

7-8 Dec., 2000 Forum for Collaborative HIV Research/ George Washington University
Workshop on Immune-Based Therapies and HIV Disease, Washington,
DC. Invited discussant.

2001

- 10 January, 2001 Institute of Human Virology, Baltimore, MD. Invited seminar speaker.
- 17-18 Jan., 2001 Genetics Institute, Cambridge, MA. Invited seminar speaker.
- 22-27 Jan., 2001 Keystone Symposium on the Interface between Innate and Adaptive Immunity, Keystone, CO. Invited plenary session speaker.
- 4-8 Feb., 2001 8th Conference on Retroviruses and Opportunistic Infections, Chicago, IL. Invited symposium speaker.
- 7-10 Mar., 2001 3rd Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy, Sabin Vaccine Institute, Walker's Cay, Bahamas. Invited speaker.
- 28 Mar.-3 Apr., 2001 Keystone Symposium on AIDS Vaccines in the New Millenium, Keystone, CO. Invited plenary session speaker.
- 1 May, 2001 Vaccine Research Center, NIH, Bethesda, MD. Invited seminar speaker.
- 2-4 May, 2001 7th National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Organizing committee.
- 4-7 May, 2001 Federation of Clinical Immunology Societies (FOCIS) Meeting, Boston, MA. Invited plenary session speaker.
- 2 July., 2001 Celera Genomics, Inc., Rockville, MD. Invited seminar speaker.
- 22-28 July, 2001 11th International Congress of Immunology, Stockholm, Sweden. Invited workshop chair.
- 27 Aug. 2001 IDEC Pharmaceuticals, La Jolla, CA. Invited seminar speaker.
- 9-13 Sept., 2001 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary session speaker.
- 27-31 Oct., 2001 13th Cent Gardes Symposium on Retroviruses of Human AIDS and Related Animal Diseases, Annecy, France. Invited speaker.
- 28 Nov.- 2 Dec., 2001 3rd Midwinter Symposium on Hepatitis C Virus, Barbados. Invited speaker and chairperson.
- 18 Dec., 2001. Pulmonary Branch, National Heart, Lung, & Blood Institute Seminar, Bethesda, MD. Invited speaker.

2002

- 16-22 Jan., 2002 Keystone Symposium on T Lymphocyte Activation, Differentiation, and Death, Keystone, CO. Invited plenary speaker.
- 6-10 March, 2002 Fourth Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy, Walkers Cay, Bahamas. Invited speaker.
- 5-11 April, 2002 Keystone Symposium on HIV-1 Protection and Control by Vaccination, Keystone, CO. Invited plenary speaker.
- 10-15 April, 2002 Keystone Symposium on Gene-Based Vaccines, Breckenridge, CO. Co-organizer and invited plenary speaker.
- 22-24 April, 2002 International Meeting on Cytokines as Natural Adjuvants: Perspectives for Vaccine Development, Rome, Italy. Invited plenary speaker.
- 1-3 May, 2002 8th National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Organizing committee
- 10 May, 2002 International Immunological Readouts Meeting (Workshop), Bethesda, MD. Invited speaker.
- 26 June, 2002 American Association of Immunologists Introductory Course in Immunology, Tufts University, Medford, MA. Invited lecturer.
- 27-31 July, 2002 FASEB Summer Research Conference on Therapeutic and Preventive AIDS Vaccines, Tuscon, AZ. Invited plenary speaker.
- 9-13 Sept., 2002 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary session speaker.
- 23-25 Oct., 2002 DNA Vaccines 2002, Royal College of Physicians, Edinburgh, Scotland. Invited plenary speaker.
- 26-29 Oct., 2002 XIIIth Cent Gardes Meeting on HIV and AIDS Vaccines, Annecy, France. Invited plenary speaker.
- 5-8 Nov., 2002 2nd International Workshop on CD1 Antigen Presentation and NK T Cells, Woods Hole, MA. Invited speaker.
- 18-23 Nov., 2002 BioSecurity 2002: Vaccines: The Paradigm Quake, Las Vegas, NV. Invited speaker.
- 25-27 Nov., 2002 Pan American Health Organization Centennial Celebration Conference on Vaccines, Washington, DC. Invited plenary speaker.

2003

- 7 Jan., 2003 NIH Academy, Invited speaker.
- 15-19 Jan., 2003 AACR Special Conference in Cancer Research: The TGF- β superfamily—roles in the pathogenesis of cancer and other diseases, La Jolla, CA. Invited plenary speaker.
- 23-24 Jan., 2003 AAI/NCI Workshop on Cancer Immunology, Bethesda, MD. Invited participant.
- 27 Jan., 2003 University of Chicago Committee on Immunology Seminars, Chicago, IL. Invited speaker
- 17-23 Feb., 2003 Keystone Symposium on Basic Aspects of Tumor Immunology, Keystone, CO. Invited speaker.
- 5-8 March, 2003 Sabin Vaccine Institute 5th Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy, Walker's Cay, Bahamas. Invited speaker.
- 13 March, 2003 Experimental Transplantation Branch, CCR, NCI, Bethesda, MD. Invited seminar speaker.
- 28 Mar-4 Apr., 2003 Keystone Symposium on HIV Vaccine Development, Banff, Alberta, Canada. Invited speaker.
- 23-24 April, 2003 Kunkel Society of Rockefeller University Annual Meeting, New York, NY. Invited plenary speaker.
- 30 Apr.-2 May, 2003 9th WRAIR National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Organizing committee
- 15-19 May, 2003 3rd Annual Meeting of the Federation of Clinical Immunological Societies (FOCIS), Paris, France. Invited speaker.
- 20 May, 2003 American Society for Microbiology Annual Meeting, Washington, DC. Invited symposium speaker.
- 1-2 June, 2003 Nobel Forum on Vaccines and Immunotherapy, Stockholm, Sweden. Invited plenary speaker.
- 29 Sept.-3 Oct., 2003 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary session speaker, special lecture.
- 14-17 Oct., 2003 MD Anderson 56th Annual Symposium on Fundamental Cancer Research: Cancer Immunity: Challenges for the Next Decade, Houston, TX. Invited plenary speaker.

1 Dec., 2003 USDA Agricultural Research Service National Immunology Conference, Bethesda, MD. Invited Keynote Speaker.

2004

6-11 Jan., 2004 Keystone Symposium on Rational Design of Vaccines and Immunotherapeutics, Keystone, CO. Invited plenary speaker.

25-30 Mar, 2004 Keystone Symposium on Immune Evasion, Taos, NM. Invited plenary speaker.

17-21 Apr, 2004 American Association of Immunologists Annual Meeting, Washington, DC. Invited Symposium Chairperson and Speaker.

29-30 Apr, 2004 10th WRAIR National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Invited Symposium Chairperson and Speaker.

13-15 June, 2004 International Workshop on Cancer Vaccines, Siena, Italy. Invited plenary speaker.

15-18 June, 2004 International Colloquium on Innate and Adaptive Immunity after Transcutaneous or Mucosal Vaccination, Veyrier du Lac, France. Invited plenary speaker.

18-24 July, 2004 12th International Congress of Immunology and 4th Annual Conference of the Federation of Clinical Immunological Societies, Montreal, Canada. Invited minisymposium speaker.

6 Sept., 2004 Queensland Institute of Medical Research, Brisbane, Australia. Invited seminar speaker.

8-13 Sept, 2004 3rd International Workshop on NKT Cells and CD1-mediated Antigen Presentation, Heron Island, Australia. Invited plenary speaker.

10-13 Oct, 2004 International Symposium on Tumor Escape and Its Determinants, Salzburg, Austria. Invited plenary speaker.

31 Oct-4 Nov, 2004 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited Symposium Chairperson and Speaker.

17 Nov, 2004 The 2004 Tadeusz J. Wiktor Memorial Lecture, Wistar Institute, University of Pennsylvania, Philadelphia, PA.

2005

- 19-24 March, 2005 Keystone Symposium on Basic Aspects of Tumor Immunology, Keystone, CO. Invited Speaker and workshop chair.
- 29 Aug-2 Sept, 2005 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited Symposium Chairperson and Featured Speaker
- 19-21 Sept, 2005 NIH Immunology Interest Group Retreat, Airlie, VA. Invited session chair and organizer.
- 22-23 Sept, 2005 International NCI Symposium on Translational Immunology Related to Cancer, Bethesda, MD. Organizer, Session Chair, and Plenary Speaker.
- 24 Oct., 2005 Albert Einstein College of Medicine, Bronx, NY. Invited seminar speaker.
- 10-11 Nov, 2005 CHAVI Conference on Mucosal Immunity and Vaccines, Duke University, Durham, NC. Invited plenary speaker.
- 16-19 Nov, 2005 First International Dead Sea Conclave on HIV and Cancer Vaccines, Dead Sea, Jordan Valley Marriott Resort and Conference Center, Jordan. Invited session chair and plenary speaker.
- 13-14 Dec, 2005 Boston University International Conference on Biodefense, Boston, MA. Invited plenary speaker.
- 16 Dec, 2005 Laboratory of Experimental Immunology, Frederick Cancer Research and Development Center, CCR, NCI. Invited seminar speaker.

2006

- 5-7 Feb, 2006 Hasumi Foundation International Symposium on Cancer Vaccines, Bethesda, MD. Invited Plenary Speaker.
- 9 Feb, 2006 NCI Symposium on Inflammation and Colon Cancer, Bethesda, MD. Invited panel discussant.
- 5-9 March, 2006 American Association for Asthma, Allergy, and Immunology Annual Meeting, Miami Beach, FL. Invited Plenary Speaker.
- 26-29 May, 2006 International Symposium on Cancer Vaccines, Naples, Italy. Invited Plenary Speaker.
- 4-8 Oct., 2006 International Conference on NKT Cells and CD1, Siena, Italy. Invited speaker.

- 30 Oct., 2006 Symposium on IL-15 and Immunotherapy, Bethesda, MD. Invited speaker.
- 17-21 Nov, 2006 10th International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary speaker and session chair.
- 2007**
- 25-28 Jan, 2007 Symposium on Immune Suppression in Cancer, Moffitt Cancer Research Center, Tampa, FL. Invited plenary speaker.
- 1 Feb, 2007 International Society for Cutaneous Lymphoma, Herschel Zackheim Memorial Lecture and Award.
- 8-9 Feb, 2007 FDA-NCI Cancer Immunotherapy workshop, Organizer and session Chair
- 15-19 Feb, 2007 American Association for the Advancement of Sciences (AAAS) Annual Meeting, San Francisco, CA. Chair-elect of Medical Sciences Section.
- 17-18 March, 2007 Symposium on Two Decades of Predictive Biology, Boston University, Boston, MA. Invited plenary speaker
- 21-23 March, 2007 Symposium on Viruses, Genes and Cancer, Venice, Italy. Invited plenary speaker.
- 12-14 April, 2007 International Cancer Vaccine Symposium, Vienna, Austria. Invited plenary speaker.
- 12-14 April, 2007 Third Vienna Vaccines Conference, Baden, Austria. Invited plenary speaker.
- 18-22 May, 2007 94th Annual Meeting of the American Association of Immunologists, Miami Beach, FL. Invited symposium speaker.
- 12-13 July, 2007 NCI Immunotherapy Workshop, Bethesda, MD. Invited speaker.
- 23 July, 2007 Viral Immunology Symposium, Johns Hopkins University School of Public Health, Baltimore, MD. Invited plenary speaker.
- 9-11 Sept. 2007 Nobel Forum on Progress in Vaccines against Cancer, Stockholm, Sweden. Invited plenary speaker.
- 27 Sept, 2007 University of Pittsburgh, Pittsburgh, PA. Invited seminar speaker.
- 9-10 Oct., 2007 NCI Center of Excellence in Immunology Symposium on Cancer and Inflammation, Bethesda, MD. Organizing committee and session chair.

- 28-30 Oct., 2007 ANRS and NIH Symposium on Mucosal Immunity and HIV/AIDS Vaccines, Annecy, France. Invited plenary speaker.
- 1-2 Nov., 2007 NCI Symposium on HIV and AIDS Research, Bethesda, MD. Organizing committee and speaker and session chair.